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INTUBATING LARYNGEAL MASK

Background of the Invention

The invention pertains to endotracheal-device placement in a patient requiring assured airway access, for breathing or anaesthetic purposes, for example, after the patient has lost consciousness with resulting compromise to the air passages, which can be life-threatening, if the airway access is not quickly and assuredly accomplished.

Endotracheal intubation using a laryngoscope is a relatively skilled procedure and inevitably involves distortion of the anatomy in order to bring the glottis into the line of sight. In addition, an endotracheal tube (ET) is designed for ease of passage when the anatomy is thus distorted; thus, curvature of the ET does not correspond with the contours of the relaxed anatomy of the patient's upper airway. Because it is not always possible or desirable to distort the anatomy, the so-called "difficult" airway remains an important cause of mortality and morbidity in anaesthesia, in spite of a plethora of intubating aids and difficult-airway algorithms.

The laryngeal mask (LMA) has found a place in this arena, but suffers from the disadvantage that its airway tube is too long and narrow to act as an acceptable conduit for intubation, in that it cannot be removed easily from the ET, once intubation has been accomplished. In addition, the mask-aperture bars (MAB) of an LMA may obstruct or deflect ET passage. Nevertheless, the LMA has the advantage that ventilation can usually be maintained, whether or not the patient can be intubated. Examples of LMA devices in prior-art patents are to be found in U.S. patents 4,509,514; 4,995,388; 5,241,956; 5,303,697*, 5,355,879; 5,477,851* (now Reissue patent Re. 35,531*); and also in pending U.S. application Serial No. 08/826,563, filed April 4, 1997*. Of these patent disclosures, those just identified by asterisk (*) deal in one way or another with various structural

improvements to facilitate use of an LMA as an aid to intubation.

Patent 5,303,697 discloses use of an intubating LMA featuring a rigid stainless-steel airway tube with an inflatable mask at its distal end. The point of the invention was to adopt as thin as possible tube-wall thickness, for purposes of accommodating a range of ET diameters, and to enable manipulation of the placement of the distal mask. The two embodiments of this patent show curvature of the rigid tube to be of differing arcuate extent, namely, either (i) a right angle or (ii) somewhat less than a right angle; and my experience in working with either of these configurations is that distortion of the anatomy was needed, e.g., by the anesthesiologist lifting the patient's neck and extending the head to seek an accommodating non-neutral* variation of spine curvature in the neck region, in order to achieve suitable conditions for LMA placement and intubation through the LMA. Such manoeuvering has at least the disadvantages of (a) requiring full mobility of the bones of the neck, and (b) inviting neurological damage if the patient has sustained a neck injury.

Brief Statement of the Invention

It is an object of the invention to provide an improved LMA construction, with specific applicability to intubation of a patient with an ET or other device.

Specific objects are to achieve the above object with an improved construction that features a rigid airway tube which accommodates natural anatomical curvature and:

(i) in which the need for head and neck manipulation can be avoided, during mask insertion and placement and during intubation;

(ii) in which the need for distortion of the anterior pharyngeal anatomy by a laryngoscope can be avoided;

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* A "neutral" head position is achieved when the head and neck are positioned, as by a pillow, so as to correspond with the patient's head/neck relation when the patient is standing upright.

(iii) in which the intubating laryngeal mask, as a unit, can be self-retaining at an anatomically correct installed position, with minimum local stress on any part of adjacently contacted anatomy;

(iv) in which the larynx can be "masked" by the LMA device without requiring finger-insertion into a patient's mouth;

(v) in which the intubation guide is easily removable without head/neck manipulation or distortion of anterior or posterior anatomical structure;

(vi) in which a more anatomically appropriate ET can be accommodated; and

(vii) in which an intermediate airway is available, prior to or during intubation attempts, or following extubation under deep anaesthesia.

The invention achieves the foregoing objectives and other advances in an intubating LMA construction which features a rigid airway tube wherein curvature in a single plane establishes essentially an arcuate path of angular extent in the range of 100° to 145°, a preference being indicated for the range 125° to 135° which I have found to represent normal anatomy in a neutral position; more specifically, I have found the range 125° to 135° to be in substantial anatomical conformance with the airway path of the adult human. The rigid tube extends between a proximal end of the arc--at substantial register with the longitudinal midpoint of the hard palate, and a distal end that faces and is at short offset from the glottic aperture, it being understood that my findings apply to suitably quantified allowance for variations in patient-head anatomy, as is for example customary for different sizes of LMA devices. The proximal end of the rigid tube is suitably a short straight portion which is tangentially and integrally related to the proximal end of the arc. And the distal end of the arc is fitted with flexible mask structure of preferably elastomeric material such as silicone rubber, wherein an internal ramp formation within the mask structure assures a limited but important measure of further and stabilized guidance of an ET which has emerged from the distal end of the rigid tube, such that unguided displacement of the ET (i.e., beyond the ramp) is oriented

to target safe entry of the ET into the glottic opening. Stated in other words, the included angle of ET guidance by the preferred embodiment of the invention is approximately 130°, plus or minus 5° , between (a) the "launch" direction of an ET emerging from ramp guidance and (b) the orientation axis of the straight proximal-end portion of the rigid tube.

Brief Description of the Drawings

The invention will be described in detail for preferred embodiments, in conjunction with the accompanying drawings, in which:

Fig. 1 is a simplified fragmentary view in side elevation and in partial section, taken in the vertical plane of symmetry, showing an intubating laryngeal mask of the invention, in schematically suggestive context of relevant features of a patient's head/neck anatomy;

Fig. 2 is a view similar to **Fig. 1**, to show relevant ET structure that has been guided by the device of **Fig. 1**; and

Fig. 3 is a schematic sectional view taken at the distal end of ramp structure, provided at the distal end of ET guidance by the device of **Figs. 1** and **2**, the section being taken in a plane normal to the path of ET guidance, to show ramp stabilization of the ET; and

Fig. 4 is a simplified view similar to **Fig. 1** to show a modification.

Detailed Description

In **Fig. 1**, an intubating laryngeal-mask (ILM) device 10 of the invention is shown installed in and self-retained by relevant features of a patient's oral anatomy. An anatomically curved rigid tube portion 11 of device 10 is suitably of bent stainless-steel tubing which may be of 13-mm minimum internal diameter, in order to accept insertion of a cuffed 8-mm endotracheal tube (ET). The curved portion 11 is suitably conformed to a circular arc α of preferably 130° $\pm$ 5°, extending from a proximal limit 12 of tube curvature to a distal limit 13 of tube curvature, the curvature being along a central axis 14 of airway passage and in a first (or vertical) geometric plane of symmetry; the maximum or outer radius R_1 of tube (11)

curvature is suitably 41.5 mm, for use by a large fraction of the adult population, for whom the minimum or inner radius R_2 of curvature is about 27 mm.

At the proximal limit 12 of curved portion 11, a straight proximal end portion 15 is an integrally formed part of the same tubing, having tangential connection to the proximal end of the arc at location 12, which is in register with substantially the longitudinal mid-point of the patient's hard palate, labeled HP in the drawing. The outer radius R_1 of curved portion 11 is shown to substantially conform to concave curvature of the patient's soft palate (SP), as also labeled in the drawing; and the inner radius R_2 of curved portion 11 will be understood to conform to convex curvature of the back of the patient's tongue (not shown).

At the distal end 13 of the curved portion 11 of the rigid tube, the central axis 14 of the airway path determined by the tube is directed toward the laryngeal inlet and is in the above-noted first or vertical plane of symmetry, said distal-end limit being at the upper region of the pharynx and at considerable offset from the intended target of ET entry into the glottic aperture, but laryngeal-mask structure 20 carried by the distal end of the rigid tube is internally configured to extend and laterally stabilize the guidance of an inserted ET, for greater assurance of the targeted entry.

The laryngeal-mask structure 20 is of flexibly yieldable elastomeric material, wherein relative thickness determines the relative stiffness or weakness of compliant deformability. Basically, structure 20 comprises a relatively stiff backing plate formation 21 having an inlet-air counterbore formation (shown, but not marked) of arcuately curved extent δ which accounts for telescopic reception and bonding of mask structure 20 to the distal end of tube 11. As shown, the arcuate extent δ of telescopic fit is 20° to 25°, which is sufficient to assure a circumferentially sealed fit and also to fully provide enclosure of a truncated radially inner-end portion of the rigid tube, the truncation being identified 22 in the drawing.

As with prior laryngeal masks, the backing plate will be understood to terminate in a generally elliptical rim of attachment to a peripherally continuous and softly compliant ring formation which, in the preferred form shown is an inflatable ring 23 having means 24 of control connection for air-inflation/deflation purposes. The elliptical rim and ring 23 will be further understood (a) to have lateral symmetry about the vertical plane of symmetry and (b) to lie generally in a second geometric plane 25 which is normal to the first or vertical plane.

Within the backing plate 21, the airway passage of the rigid tube 11 is seen to be effectively extended by a ramp formation 26 of V-section and of progressively increasing depth, beginning at substantially tangential relation to the adjacent end of the tube bore at the outer radial limit (R_1) of rigid tube curvature; by reason of its sectional symmetry about the above-noted first geometric plane of symmetry, ramp formation 26 will be seen to serve the dual purpose of stabilizing an ET in the course of its insertional advance beyond the distal end of tube 11, while at the same time providing a substantially shortened offset distance for otherwise unsupported projection of the distal end of an ET, beyond the distal end of ramp formation 26, for better-controlled targeting of ET entry into the glottic opening. **Fig. 3** schematically illustrates stabilizing support for an insertionally advancing ET, wherein the Vee of ramp 26 is seen to provide side walls 26' which symmetrically diverge from the central plane of symmetry, the included angle of Vee spread between the walls of ramp formation 26 being suitably in the range 150° to 165°.

The thus-extended advancing guidance of ET insertion is also seen in the drawing to involve ET encounter with a compliantly and effectively hinged tongue formation 27 which may be an integral formation of backing plate 21, but which has been shown with a different direction of cross-hatching, for better identification of parts in the drawing. Tongue formation 27 will be understood to have lateral symmetry about the first geometric plane of symmetry and to be of lateral extent which is less than the bore diameter of tube 11, thus permitting free airway communication to the glottis and through device 10, once ring 23 has been

inflated to develop a seal around the laryngeal inlet. However, the compliant hinging of tongue 27 at 28, on an effective hinge axis in plane 25 and perpendicular to the first geometric plane, enables an advancing ET to drive tongue 27 (clockwise, in the sense of the drawing) for deflecting the patient's epiglottis 30 out of the path of the ET as it advances toward the targeted glottic opening.

It will be seen that in general terms, the fact of ET clearance within the inside diameter of the rigid airway tube necessarily means that at exit from the rigid tube, the ET may be at minor misalignment with resepct to the orientation of the central axis 14 at the distal or exit end of the rigid tube; however, the existence and action of the described ramp 26 are such not only to assure ET-centering between opposed ramp walls 26, but also to effect such a ramped deflection of the ET (at ET exit from the ramp) as to substantially offset, minimalize, or correct for the minor misalignment noted at ET exit from the distal end of rigid tube 10. Thus, at launch from the exit end of the ramp, the ET can be more assuredly projected for targeted entry into the glottic opening.

Description of the device of **Fig. 1** is completed by identification of a rigid handle 35, secured to the externally projecting proximal end portion 15 of the rigid airway tube 10; handle 35 (preferably sufficiently malleable to enable a technician to adjust handle orientation to suit his individual preference) serves for manual manipulation of tube 10 and its distal mask structure 20; and it will be understood that the open proximal end of portion 15 is adapted by means of an inwardly tapered contour 15' to fit standard ventilating or anaesthetizing equipment for accessing the patient's lungs, as needed. Further preference is indicated for an elastomeric cladding or coating of tube 10, as suggested by cross-hatching 36 in **Fig. 1**.

In use, the device 10 is grasped via handle 35, and the inflatable ring 25 is deflated to define a suitably flexible lip which will smoothly adapt to the patient's airway, as device 10 is being inserted. Once the flexible lip enters the mouth, it naturally and flexibly adapts to hard-palate and soft-palate curvatures on its way to the pharynx, and

the truncation 22 of the distal end of the rigid tube enables flexed compression of the mask/tube junction for ease of passage through a narrowed inter-dental gap. In the course of such insertion, it will be appreciated that manipulation of the straight proximal end 15 undergoes a bodily angular displacement (clockwise, in the sense of **Fig. 1**) about the center C of arcuate portion 11, as said portion 11 is sensed to be in very substantial conformance with the patient's oral anatomy, all the way to the pharynx, thus positioning the distal orientation of tube-11 exit in near-register with the glottic opening. The limit of such angular displacement occurs when the straight proximal end 15 abuts upper tooth structure, e.g., the patient's incisors (33). This event will be recognized as a stop whereby to know that insertion has been completed as far as needed, and ring 23 may be immediately inflated, to establish a peripherally sealed adaptation at and surrounding the laryngeal inlet, with ramp (26) oriented for immediate insertion of an ET device, it being noted that, once ring 23 has been inflated to establish its seal to and around the laryngeal inlet, airway access to the patient's lungs has been provided. On exit from ramp (26) guidance, further displacement of the ET device encounters the compliantly hinged tongue 27, to assure that the epiglottis is lifted out of possible encounter with the advancing ET device, as seen in **Fig. 2** for the ET device 32. When the ET device has entered the glottic opening, it can pass the vocal cords and be sealed by inflation of its cuff, as is customary.

After the ET has been sealed in its installed position, the ET can accommodate all patient-ventilating/anaesthetizing purposes. In some clinical circumstances, the intubating laryngeal mask (ILM) can be left in place during the procedure. When the patient has had all use that is needed for the ET, and after its seal cuff has been deflated, ET removal is then a simple matter of extraction via the guide passage established by mask 20. After ET extraction, the device of **Figs. 1** and **2** may then resume its patient-ventilating function, with the hinged tongue 27 compliantly returning to its position of **Fig. 1**, whereby to avoid epiglottis blocking of the airway; and a resumed

intermediate airway can be established for patient ventilation. This procedure may be appropriate when extubation is judged to be best performed while the patient is still under deep anaesthesia. However it is also possible and sometimes desirable to remove the ILM while the ET remains in place. In this case, the ET cuff remains inflated and the ILM cuff is deflated prior to removing the device, following the same circular arc as is followed for insertion. To prevent accidental ET dislodgement, the ET is meanwhile held in place by counterpressure supplied by a short flexible rod abutting against the outer end of the ET as the metal tube is slid over it.

It has been indicated above that, for most cases, a single rigid tube 10 may well serve patients for whom different elastomeric distal-mask components may be fitted, thus serving patients having different oral-cavity geometries and proportions. In some cases, however, and in particular for a patient who can be readily recognized as having an unusually long neck, it is recommended to follow the described rigid-tube configuration of **Figs. 1** to **3**, subject to a single modifying departure, at the tube location at which a tangent to the convex outer profile of the tube is locally parallel to (or near-parallel to) the alignment of the patient's vertebrae. Such a condition is illustrated in **Fig. 4**, wherein the arcuate extent α of rigid tube 10 is seen to have been divided into a first and larger proximal arc α_1 about a first center C_1, and a second and shorter distal arc α_2 about a second center C_2. Radius of curvature is the same for both arcs α_1 and α_2, and the centers C_1 and C_2 are on a geometric alignment that is essentially parallel to the alignment of locally adjacent vertebrae. Thus, a straight section 37 is effectively aligned essentially parallel to the alignment of adjacent vertebrae, and this straight section 37 is integrally and tangentially united with the adjacent ends of the arcs α_1 and α_2. In **Fig. 4**, all other structural features of **Figs. 1** and **2** apply, as described above.

It is noted that the laryngeal opening into and through which the described intubating laryngeal mask provides guided entry is a relatively tolerant anatomical feature for the human adult, in that in terms of a geometric direction

suggested by downward extension of line 12 in **Figs. 1** and **2**, there is a span between an upper limit established by the epiglottis and a lower limit associated with arytenoid cartilages, wherein said span may extend, typically approximately 20-mm, for target acceptance by the laryngeal opening of an ET launched from the described mask structure. What is accomplished by the structure of **Fig. 4** is a predetermined (illustratively 10-mm) further downward offset of the ET-launch point, for the case of a person having a recognized longer-than-usual neck, it being understood that such recognition can be readily deduced from external observation of the patient's "Adam's apple" in relation the patient's maxillary structure.

The described intubating laryngeal-mask devices will be seen to meet all stated objects. Mask removal follows deflation of ring 20, followed by an extraction manoeuver wherein the straight proximal portion undergoes counterclockwise bodily displacement about the center C. As long as the patient has first been supported in supine position, as with a suitable pillow to assure a "neutral" orientation of the upper region of his spine (i.e., adjacent regions of his head, neck and body), there is no need to manipulate the spine, i.e., the patient's head with respect to his body, either in the course of mask insertion/removal or in the course of ET insertion/removal, thus assuring minimum risk to a patient whose spine has been injured, and thus also removing the major cause of difficulty in intubation of the trachea when immobility of the neck makes it difficult to use a laryngoscope to locate the glottis.

A significant feature of the present invention is the fact that a single manufactured size of the rigid airway tube 10, of bent tubing having a minimum inner diameter of 13-mm, with its arcuate extent in the range 130° plus or minus 5°, and at a minimum outer radius (R_1= 41.5 mm) about a common center (C), can be assembled with a selected one of three standardized distally fitted LMA inflatable-mask sizes, namely, a selected one of the sizes 3, 4 and 5 which have become standardized on the following basis:

Size 3, for children and small adults, weighing in the range 30 to 50 kg;

Size 4, for adults weighing in the range 50 to 70 kg;

and

Size 5, for adults weighing more than 70 kg.

From the point of view of manufacturing economy, this circumstance portends satisfying anatomy requirements of the vast majority of patient's requiring intubation, all using the same size rigid tubing, but fitted with different selected distal inflatable mask sizes, selected from the indicated grouping.

It is also possible that similar economies of rigid airway tube (10) construction can be achieved for remaining standardized LMA sizes, namely, sizes 1, 1.5, 2, and 2.5.